4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2018-F-3230]

Oakshire Naturals LP; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Oakshire Naturals LP, proposing that the food additive regulations be amended to provide for the safe use of vitamin D_2 mushroom powder as a nutrient supplement in specific food categories.

DATES: The food additive petition was filed on July 16, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 8A4821), submitted by Oakshire Naturals LP, 295 Thompson Road, P.O. Box 388,

Kennett Square, PA 19348. The petition proposes to amend the food additive regulations in part 172 (21 CFR part 172) *Food Additives Permitted for Direct Addition to Food for Human Consumption* to provide for the safe use of vitamin D_2 mushroom powder, produced by exposing homogenized edible mushrooms to ultraviolet light, as a nutrient supplement in: (1) foods to which vitamin D_2, vitamin D_3, and vitamin D_2 bakers yeast are currently allowed to be added under 21 CFR 184.1950, 172.379, 172.380, and 172.381 (excluding cheese and cheese products, foods represented for use as a sole source of nutrition for enteral feeding, infant formula, milk and milk products, and margarine); (2) fruit smoothies; (3) vegetable juices; (4) extruded vegetable snacks; (5) soups and soup mixes (except for those containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act); and (6) plant protein products as defined in 21 CFR 170.3(n)(33).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: September 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20217 Filed: 9/17/2018 8:45 am; Publication Date: 9/18/2018]